



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,503	11/02/1999	THOMAS R. CECH	15389-002611	1130
34151	7590	07/28/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP			ANGELL, JON E	
8TH FLOOR			ART UNIT	
TWO EMBARCADERO CENTER			PAPER NUMBER	
SAN FRANCISCO, CA 94111			1635	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,503

Applicant(s)

CECH ET AL.

Examiner

Jon Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1635

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 4/7/04 and 5/5/04 have been entered.

Claims 1-40 have been cancelled. Claims 41-91 are currently pending and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/12/04 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 58 recite the phrase, “a recombinant polynucleotide that encodes a telomerase reverse transcriptase protein comprising SEQ ID NO: 2, **or a fragment thereof** having telomerase catalytic activity when complexed with a telomerase RNA” (emphasis added). The claim is indefinite because it is unclear whether the phrase “a fragment thereof” refers to a fragment of the polynucleotide or a fragment of SEQ ID NO: 2 (a polypeptide). Amendment of the claim to clearly indicate either that the claim is drawn either to “a fragment of said nucleic acid” or “a fragment of said protein” would obviate this rejection. Claims 41-57 and 59-91 are rejected because they depend on claims 41 or 58.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

Art Unit: 1635

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A careful analysis of the phrase "a polynucleotide that encodes a telomerase reverse transcriptase protein comprising SEQ ID NO: 2, or a fragment thereof having telomerase catalytic activity when complexed with a telomerase RNA" reveals that the claim encompasses not only a polynucleotide that encodes SEQ ID NO: 2, but also a polynucleotide that encodes only a fragment of SEQ ID NO: 2 as well as other sequences such that the polynucleotide encodes a polypeptide that has telomerase catalytic activity when complexed with a telomerase RNA. Given the broadest reasonable interpretation, the claim encompasses a polynucleotide that encodes only a couple amino acids of SEQ ID NO: 2, and also encodes any other amino acid sequence which has telomerase catalytic activity when complexed with a telomerase RNA. Therefore, given the broadest reasonable interpretation the claims encompass a genus of polynucleotide sequences that comprise sequences different from those disclosed in the specification, and includes a vast number of different sequences considering that the genus includes all known telomerase reverse transcriptase (TRT) genes, including TRTs of different species as well as yet to be identified TRT genes and all possible functional variants of these TRT genes (including allelic variants, fragments, etc.).

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical

Art Unit: 1635

properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

As indicates above, the claims encompass a genus comprising a huge number of different sequences wherein the sequence encodes a polypeptide that has at least a fragment of SEQ ID NO: 2 and wherein the polypeptide has telomerase catalytic. As such the genus of polynucleotides includes all sequences that encodes for a polypeptide that has telomerase catalytic activity—including yet to be identified TRTs, allelic variants, as well as any fragments/mutants that are functionally active.

It is acknowledged that the specification has identified a few different TRT genes, including human TRT (hTRT) as well as well as TRT genes of *S. pombe* (tez1), *S. cerevisia* (EST2), *Euplotes aediculatus* (p123) (e.g., see Fig. 1). It is also acknowledged that the specification also indicates potential functional domains of the TRT genes based on sequence homology (e.g., see FIG. 1, 2 and 4). However, with respect to identifying the functional domains, the instant specification appears to only indicate that should any of the potential domains be deleted, the catalytic function of the protein is lost. This does confirm that the domain is a critical domain; however, the specification does not appear to disclose which TRT domains constitute the minimal number of elements required for full catalytic function of the protein. Furthermore, the specification does not disclose which specific amino acids of the protein are critical for function such that one of skill in the art would readily recognize which amino acids could be deleted or changed (and if changed, to which amino acids) and still result in a catalytically active protein.

Art Unit: 1635

In view of the vast number of different sequences encompassed by the claims and the limited disclosure of the specification, it is concluded that the specification has not sufficiently described a "representative number" of the species (sequences) encompassed by the claims.

Additionally, claims 41-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, in view of the written description rejection above. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As mentioned above, the claims encompass sequences for which there is insufficient written description provided in the specification, and includes sequences that are different from those disclosed in the specification and encompasses sequences which have yet to be identified. Without a clear indication of the sequences encompassed by the claims, one of skill in the art would not know how to make/use the claimed invention without performing an undue amount of additional experimentation to first be able to identify the sequences encompassed by the claims.

Separately, claims 41-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for increasing the proliferative capacity of a mammalian cell, comprising introducing into said cell a vector operably linked to a recombinant polynucleotide sequence comprising SEQ ID NO: 1,

wherein said cell is in vitro and comprises a telomerase RNA,

Art Unit: 1635

whereby introducing said vector into said cell increases the proliferative capacity of said cell, in vitro;

does not reasonably provide enablement for the full scope of the claims. For instance, the method is not enabled for in vivo embodiments, or for when the polynucleotide is not operably linked to a promoter element, or wherein the mammalian cell does not comprises telomerase RNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

Given the broadest reasonable interpretation, the nature of the invention is biomedical therapy and includes gene therapy for treating humans having disease or disorder.

The breadth of the claims

As indicated above, the claims are very broad and encompass methods for increasing the proliferative capacity of mammalian cell by administering to the cell a polynucleotide that

Art Unit: 1635

encodes a polypeptide that has telomerase catalytic activity when complexed with a telomerase RNA. A careful reading of the claim language also reveals that the claim does not explicitly require that the target mammalian cell have the Telomerase RNA required for TRT catalytic activity. Claims 58-91 encompass the method wherein the mammalian cell is in vivo. With respect to the in vivo embodiments of the claims, it is respectfully pointed out that the only contemplated use for the method described in the specification is for treating disease/disorder. As such, the only contemplated use for the method is for gene therapy to treat a disease/disorder. With respect to treating a disease/disorder, it is respectfully pointed out that the claims are not limited to treating any particular specific disease and the specification specifically contemplates treating a vast array of different diseases including: cancer, Alzheimer's disease, Parkinson's disease, stroke, graying of hair, hair loss, wound healing, osteoporosis, age-related immune system impairment, atherosclerosis, diabetes, muscle atrophy, etc. (e.g., see p. 98-100). Furthermore, the claims do not specifically indicate how the polynucleotide is delivered to the cells; therefore, the claims embrace any type of administration/delivery of the therapeutic molecule. Therefore, given the broadest reasonable interpretation of the claims, the claims encompass a method for treating any disease/disorder using the claimed method by any means of administration.

The unpredictability of the art and the state of the prior art

With respect to claims as they read on administering a polynucleotide comprising a sequence encoding a catalytically active TRT, one of skill in the art would be fully aware that in order for the polynucleotide to express the encoded polypeptide in a cell, the sequence encoding the polypeptide must be operably linked to transcriptional control elements (such as

Art Unit: 1635

promoter/enhancer elements). If the polynucleotide sequence is not operably linked to transcriptional control elements, then one of skill in the art would not expect the sequence to be expressed.

With respect to the claims as they encompass administering the polynucleotide to cells that do not comprise Telomerase RNA, it is respectfully pointed out that the specification indicates that the activity of TRT requires the presence of the Telomerase RNA (TR) to function as a template for initiating the catalytic activity of TRT. Therefore, one of skill in the art would recognize that in order for the claimed method to work, the target cell must comprise the required telomerase RNA.

With respect to the claims as they encompass in vivo embodiments (as indicated above) the claims encompass gene therapy for treating disease. Regarding gene therapy as a whole, the art at the time of filing considered gene therapy to be unpredictable as modes of delivery that would provide efficient expression of genes encoding the therapeutic polypeptide sufficient to provide an alleviation of symptoms related to the target disease or condition had not been developed. Currently, the state of the art of gene therapy is still in its infancy as the art is plagued by unpredictability. For instance, ANDERSON (Nature 392(Suppl):25-30; 1998) teaches,

“Except for anecdotal reports of individual patients being helped, there is still no conclusive evidence that a gene therapy protocol has been successful in the treatment of a human disease (p.25, first paragraph)... The challenge is to develop gene therapy as an efficient and safe drug-delivery system. The goal is more difficult to achieve than many investigators had predicted 5 years ago. (p. 25 , second paragraph)... Several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered. The reason for the low efficiency of gene transfer and expression in human patients is that we still lack a basic understanding of how vectors should be constructed, what regulatory sequences are appropriate for which

Art Unit: 1635

cell types, how in vivo immune defenses can be overcome and how to manufacture efficiently the vectors we do make.”(See p. 30).

With respect to using TRT for gene therapy, the relevant art indicates that there are a number of problems that must be overcome in order for TRT gene therapy to be considered predictable. For instance, HORNSBY et al. (J. Anti-Aging Med, 2000) teaches,

“The use of telomerized cells depends on expression of (hTERT) not causing changes that predispose cells to abnormalities of any kind, particularly neoplastic conversion. Since the initial reports of telomerization, conflicting data have been presented with respect to risks of abnormalities in cells that have been telomerized... The data that have been obtained so far do not unequivocally show the (hTERT) is able to immortalize cells without the production of any abnormalities... Other data, in fact, suggest that immortalization by (hTERT) could predispose cells to neoplastic transformation. Most significant is the finding that expression of (hTERT) is required for full tumorigenicity in human cells also expressing mutated Ras and large T/small t antigens from SV40... Considering the available data, we cannot yet predict whether telomerized cells transplanted into a host animal do in fact present a cancer risk; this can only be determined directly by long-term observation, and this has not yet been done.” (See p. 412)

HORNSBY also teaches,

“The future prospects for the use of telomerized cells are significant. As emphasized here, major efforts need to be made to be sure that telomerization is safe when applied to cells for use in human therapy.” (See p.416)

OSTLER et al. (J. Ped. Endocrin. & Metab., 2000) teaches that telomerase (hTERT) has been shown to halt telomere shortening and is sufficient to prevent senescence in at least three human cell types (fibroblasts, vascular endothelial cells and retinal pigmented cells) conferring first extended life span and then formal immortality (e.g., see last paragraph p. 1472).

Regarding telomere-driven senescence mechanisms in other mammals, OSTLER teaches,

“It is unlikely, however, that this [telomere-driven senescence] mechanism operated in rodent species. Rodents have much greater mean telomere lengths than humans, a significant spontaneous escape frequency from senescence (10⁻⁶/cell/generation compared with 10⁻¹²/cell/generation in humans) and (more seriously) some rodent

Art Unit: 1635

fibroblasts have been shown to undergo senescence in the presence of active telomerase.” (See p. 1473, first paragraph).

Regarding the possible use of Telomerase for therapeutic purposes, OSTLER teaches,

“There is considerable popular interest in the potential application of telomerase to tissue engineering and anti-aging therapies. Leaving aside the practical difficulties of the safe use of telomerase, it is clear that ectopic expression of the enzyme (or even transient telomerase reactivation) should not be treated as a ‘one size fits all’ intervention for compromised replicative capacity in every tissue.” (See p. 1474).

Therefore, it is clear that the relevant art recognizes that treating diseases that are contemplated by the specification is harder than merely increasing the proliferation of cells associated with the disease and a number of different factors have to also be considered and addressed before TRT gene therapy can be considered a predictable art.

Working Examples and Guidance in the Specification

The specification shows the nucleic acid (and amino acid) sequences that encode a few different TRT genes from different species, and indicates the potentially conserved homologous domains of the different TRTs (e.g., see Fig. 4). The specification also shows that expression of hTRT in different cells types, wherein the cells are in vitro (e.g., see Fig. 5 and Example 2). The specification also shows that the co-expression of hTRT and hTR are required for telomerase catalytic activity in a cell, in vitro (that is, both TRT and the Telomerase RNA are required) (e.g., see Fig. 10). The specification, however, does not have any working examples wherein the target cells are in vivo. Furthermore, the specification does not show how the polynucleotide encoding the TRT can be administered to the correct target cell in vivo, and how to avoid transformation of non-target cells in vivo. The specification does not indicate any specific functional variants or fragments of hTRT that can be used in the claimed method. The

Art Unit: 1635

specification does disclose that deleting certain specific domains of the polypeptide eliminates the catalytic activity of the protein, but there is no evidence presented indicating that any specific fragment or variant of hTRT (i.e. SEQ ID NO: 2) has catalytic activity when expressed in a cell. The specification also does not offer any guidance with respect to expressing the catalytic molecule in a cell wherein the polynucleotide encoding the catalytic molecule is not operably linked to expression control elements (such as in a vector).

Quantity of Experimentation

Considering the vast breadth of the claims, an enormous amount of additional experimentation would be required in order for one of skill in the art to be able to predictably use the claimed invention to its full scope. For instance, additional experimentation would be required in order to be able to use the claimed method to treat a mammal having a disease/disorder. Considering the problems recognized in the art at the time of filing and in the post-filing art (indicated above), it is clear that the additional experimentation would not be a matter of "routine experimentation". Furthermore, the evidence presented in the instant specification (e.g., see Fig 10) indicates that in order to produce a telomerase catalytic activity in a cell both the TRT and TR genes must be expressed in the cells (i.e., the cells must have both the telomerase enzyme and the telomerase RNA unit). However, the claims do not explicitly indicate that the target cell expresses both TRT and TR. Therefore, additional experimentation would be required in order to be able to practice the claimed method in a cell that does not express TR. Again, this would not be a matter of routine experimentation. Furthermore, the claims do not explicitly indicate that the polynucleotide encoding the telomerase polypeptide is operably linked to transcriptional control elements (such as a vector). Since one of skill in the art

Art Unit: 1635

would be aware that this was required to properly express the recombinant gene in a cell, additional experimentation would be required.

Level of the skill in the art

The level of the skill in the art is deemed to be high, considering the complex nature of biomedical therapy.

Conclusion

Considering that the claims are extremely broad such that they encompass methods that can be performed either in vitro or in vivo, and considering that the in vivo embodiments of the claims encompass treating a vast number and different types of diseases wherein the mere increasing of the proliferation of the cells associated with the disease would not be expected to result in treatment of the disease, the claims are not enabled to the full scope that they embrace. That is, considering the nature of the invention (gene therapy) and the vast breadth of the claims (treating any disease via any type of administration) in view of the teaching in the art that gene therapy is unpredictable and in view of the limited working examples and guidance provided at the time filing, as well as the high degree of skill required to practice the claimed invention, it is concluded that the amount of experimentation required to perform the broadly claimed invention is undue.

Response to Arguments

The previous rejections of record are withdrawn in view of the new rejections set forth above. Therefore, the Applicants' arguments are responded to the extent they pertain to the new

Art Unit: 1635

rejections set forth above. Applicant's arguments filed 4/7/04 as well as the arguments filed 2/26/03 have been fully considered but they are not persuasive.

Applicants' arguments appear to be centered on the notion that "the only question whether a different result would be expected if a TRT polynucleotide is introduced into a cell in vivo" (see p. 9 of the reply filed 4/7/04). However, the Examiner would like to point out that this is not a fully accurate description of the issue. Considering that the claims are read in light of the specification, the issue is not simply a matter of whether or not a different result would be expected if a TRT polynucleotide were introduced into a cell in vivo. This is because the only use for the claimed method in vivo contemplated in the specification is for treating a disease or disorder in a mammal. Therefore, the issue is not simply whether the method would have the same result in vivo, but is the claimed method fully enabled for treating a disease or disorder in a mammal (i.e., in vivo methods) to the full scope encompassed by the claims.

If the Applicants do not agree that the intended use for the in vivo method is for treating disease/disorders in a mammal, Applicants are asked to indicate the other use(s) the method could have in vivo, and to also specifically indicate where in the specification (by page and line numbers) support can be found for the other asserted in vivo utilities.

Since the specification at the time of filing only contemplates using the claimed method in vivo for treating a disease or disorder, the claims are properly rejected under 35 USC 112, first paragraph for the reasons set forth above.

With respect to Applicants arguments that Adenoviral vectors and retroviral vectors could be used for increasing cell proliferative capacity; it is acknowledged that those vectors could be used in vitro. However, the specification at the time of filing does not indicate how the

Art Unit: 1635

vectors could be used in vivo to specifically deliver the polynucleotide to the proper target cell or how to avoid transforming non-target cells as well as how the vectors will evade the hosts' immune system.

In response to the Declaration of Dr. Harley, as indicated above, the issue is not simply whether or not successful introduction of the TRT vector into cells in vivo would increase the proliferative capacity of the cells, but more specifically whether the method could successfully introduce the TRT vector into the proper target cells in vivo AND result in the proper expression of the therapeutic polypeptide such that the method results in treating a disease/disorder in the mammal.

With respect to the publication of Rudolph, the reference was published in 2000, after the filing date of the instant application. It is respectfully pointed out that the claimed invention must be enabled by the specification at the time of filing. Furthermore, it appears that Rudolph teaches that the delivery of a nucleic acid encoding telomerase RNA subunit (TR) was delivered. Although the telomerase RNA encoded by TR is a critical element of a functional telomerase enzyme, it is distinct from the TRT gene. Therefore, the results do not necessarily enable the instant claims. Furthermore, it is respectfully pointed out that the instant claims are not limited to treating cirrhosis of the liver, nor are the methods specifically limited to the vectors used or the routes of administration taught by Randolph. Furthermore, it is not clear that the specification at the time of filing even described the vector and the specific method of delivery utilized by Rudolph or if the specification contemplated these elements specifically for treating liver cirrhosis.

With respect to Dr. Harley's Declaration and the description of treating rabbit wounds, it is respectfully pointed out that the instant specification at the time of filing did not sufficiently describe any method including proper vectors as well as routes of administration, such that one of skill in the art would be able to practice the method for treating wounds. Based on the disclosure of the specification at the time of filing additional experimentation would be required in order to practice the claimed invention to their full scope. Furthermore, Applicants are respectfully reminded that the instant claims are not limited to treating wounds using the specific vectors and administrations described in the Declaration.

With respect to the Declaration of Dr. Irving, it is acknowledged that one of skill in the art would have known at the time of filing how to make a vector such as an adenoviral vector or retroviral vector that operably encodes hTERT. However, the claims are not limited to a vector that expresses hTERT, or to any other known TERT, but encompass vectors that operably encode any variant of TERT that has functional catalytic activity. Based on the disclosure of the specification, one of skill in the art would not have known at the time of filing which variants could be used to make a vector that encodes a functional telomerase enzyme. Furthermore, simply making the vector would fully enable the claims for treating a disease in vivo as there is no guidance on how to deliver the vector specifically to the target genes, or even which diseases could be treated using the method.

The Examiner would like to make it clear that the instant rejection is based on the breadth of the claims—specifically the claims encompass treating any disease/disorder by administering a polynucleotide encoding TERT to the individual by any route of administration. Since the

Art Unit: 1635

claimed method must be enabled at the time of filing, the specification must describe how to make/use the claimed invention to its full scope.

If the Applicants believe that the originally filed specification specifically indicates how to treat a specific disease in vivo, they are asked to identify exactly where in the specification (by page and line number) the enabling disclosure is found. Should such an enabling disclosure exist, Applicants are asked to consider amending the claims so that they are limited to treating the specific disease/disorder using the specific details described in the specification at the time of filing (such as the specific vector(s) used including the specific polynucleotides comprised in the vector, the specific method of delivering the vector to the appropriate target cell).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art Unit 1635



DAVE T. NGUYEN
PRIMARY EXAMINER